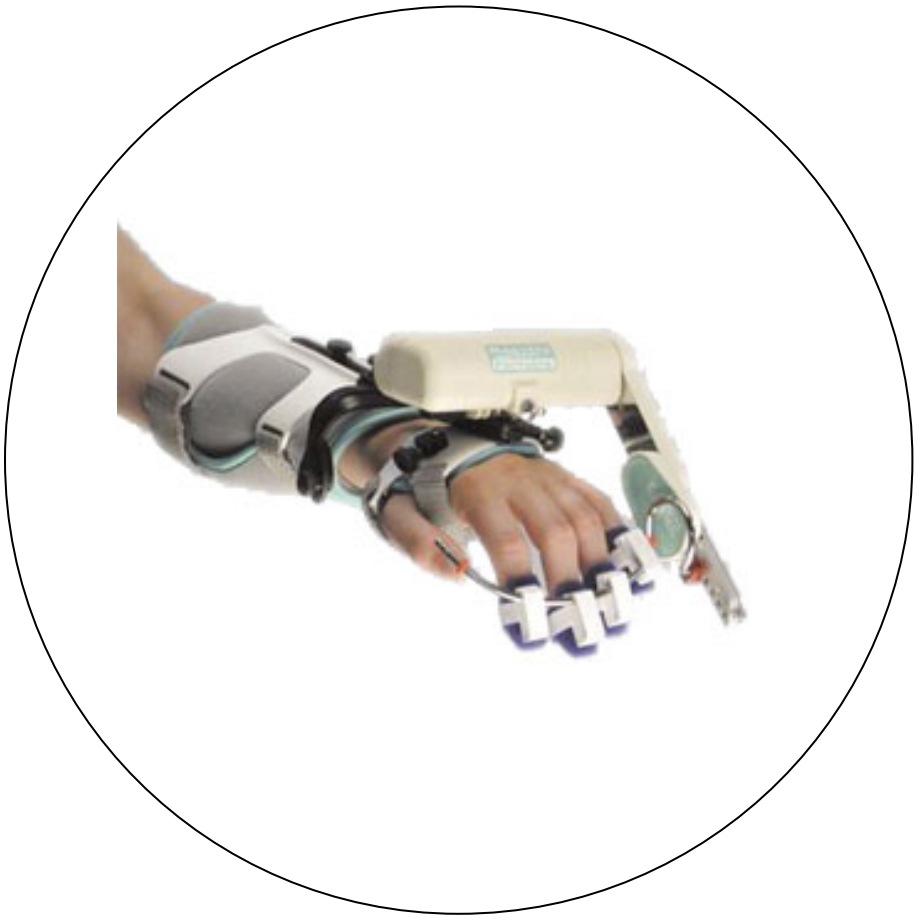
The CPM concept



Maestra Portable

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SAFETY RECOMMENDATIONS

- The physician defines the protocol and ensures that it is correctly implemented (adjustments, session time and frequency of use).
- We recommend that you lock the hand control when you give it to the patient.
- For optimum safety, always give the hand control to the patient before starting the system.
- Explosion hazard: KINETEC Maestra Portable is not designed for use in the presence of flammable anesthetics.
- Check that the electrical socket is in good condition and is suitable for the splint power supply cord. The latter complies with current standards and has a grounding socket. The plug may be connected to any standard socket. The socket must however have a grounded pin. To connect the power supply, only use the original cable supplied with the machine. Check that the cables remain free around the device so that they do not get damaged.

Manuel N°467896286 - Update 28/06/11

Definition

The KINETEC Maestra Portable is a LONG FINGERS PASSIVE mobilization device enabling the following movements:

- Simultaneous flexion-extension of the three joints: MP, PIP, DIP
- Intrinsic – (PIP, DIP)
- Intrinsic + (MP)

• Indications

- Flexor and extensor tenolysis.
- Aponeurectomies for Dupuytren disease.
- Metacarpophangeal arthrolysis.
- Open reduction and internal fixation of intra-articular, diaphyseal, metaphyseal and epiphyseal fractures of the phalanges.
- Prosthetic replacement of the MCP, PIP and DIP joints.
- Rheumatoidal/neurological or after-burn stiffness.
- Capsulotomies, arthrolysis and tenolysis for post-traumatic stiffness of MCP, PIP and SIP joints.
- Synovectomies.

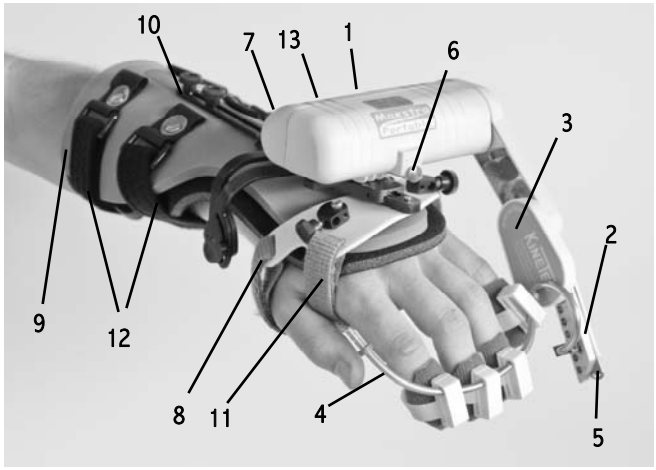
• Clinical Benefits

- Breaks the cycle of trauma, inflammation and the loss of range of motion.
- Prevents joint stiffness.
- Speeds the recovery of post-operative range of motion.
- Maintains the quality of the joint surface.
- Reduces pain and edema.
- Promotes joint cartilage healing.
- Reduces hospitalization time
- Reduces the need for pain medication.
- Provides immediate post-operative continuous passive motion.
- Digital ROM readout on the patient hand control for positive reinforcement.
- Maintains desired positions for stretching and muscular rest

• Contraindications

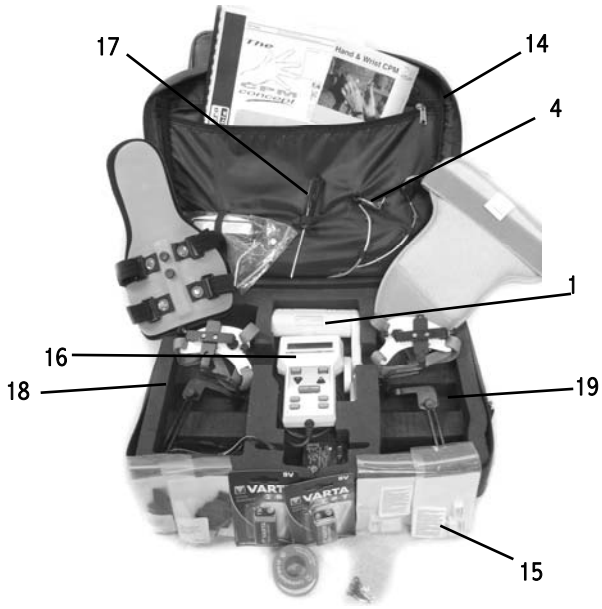
Bone Cancer, Warped joint surfaces, Spastic paralyses, Unstable fractures, Uncontrolled infection.

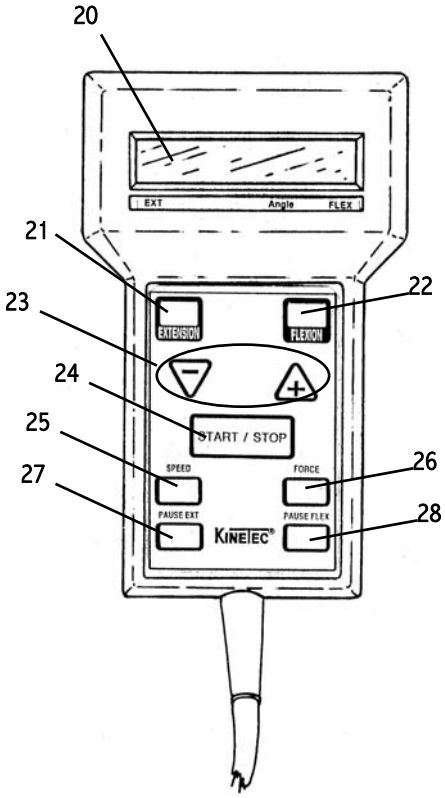
The KINETEC Maestra Portable is a portable machine, single unit device that can be used on ambulatory patients.
It consists of the following components:



1 • Motor assembly.
2 • Drive arm.
3 • Articulating joint.
4 • Curved bar.
5 • Bar locking lever.
6 • Motor stop knob.
7 • Start / Stop / Reverse button.
8 • Hand splint.
9 • Arm splint.
10 • Splint connecting bar.
11 • Hand splint strap.
12 • Arm splint starps.
13 • Handcontrol connector.

14 • Transport bag.
15 • Finger wraps.
16 • Hand control.
17 • Screw driver.
18 • Complete left splint.
19 • Complete right splint.





20 • Liquid-crystal display (1 line of 16 characters).
21 • Extension limits setting.
22 • Flexion limits setting.
23 • Increase / decrease keys.
24 • Start/Stop/Reverse key.
25 • SPEED key.
26 • FORCE key.
27 • Extension PAUSE key.
28 • Flexion PAUSE key.

Safety

The physician defines the protocol and ensures that it is correctly implemented (adjustments, session duration and frequency of use).
The patient must know the start/stop/reverse function on the control handle. Hand control must be accessible to patient at all times. (See page 5).
KINETEC Maestra Portable complies with Directive 93/42/CEE.

EXPLOSION HAZARD:
KINETEC Maestra Portable is not designed for use in the presence of flammable anesthetics.

In case of electromagnetic interference with other devices move the device.
KINETEC Maestra Portable is in compliance with standards in force (IEC 601.1.2), electromagnetic compatibility standard for medical devices.

Electrical Connection- Power Supply

The KINETEC Maestra Portable is a type B, class II device.
Power is supplied either:

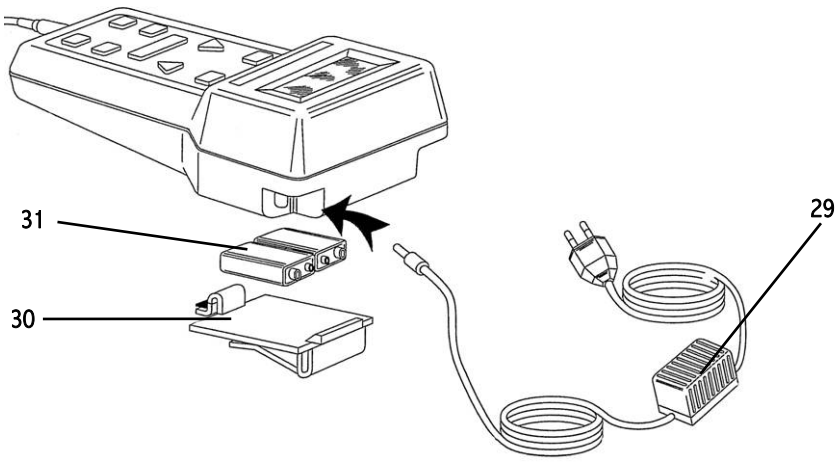
- by the external power supply box KINETEC (29) (THE USE OF ANY OTHER BOX IS PROHIBITED).
  - 4610006296 • 230V 50Hz 9V transformer,
  - 4610006444 • US Transformer plunger 120V.

  Plugged into a 230/120 volts 50/60Hz socket, Voltage of the KINETEC Maestra Portable: 9 volts direct current 150mA (power consumption: 1,5 to 7VA).
  Use a fuse of the same kind and same rating (T160mA). The fuse is inside the power supply box.

IMPORTANT
Check that the electrical socket is in good condition and is suitable for the splint power supply cord. The latter complies with current standards and has a grounding socket.
The plug may be connected to any standard socket.
The socket must however have a grounded pin.
To connect the power supply, only use the original cable supplied with the machine.
Check that the cables remain free around the device so that they do not get damaged.

- by 2 x 9 volt 6LR 61 alkaline batteries (31) (housing fastened by cover 30).
- by 2 x 6F22 8.4 volt 110mAh accumulators (housing fastened by cover 30).

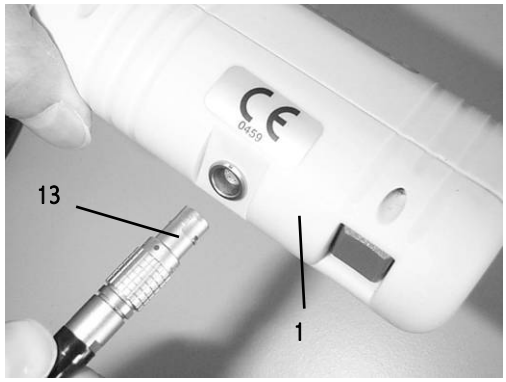
If the device is not being used for an extended period, remove the batteries or accumulators.
Note: Do not throw used batteries or accumulators into a fire.



Connecting to the motorization unit

Plug the connector (13) into the motor assembly (1), lining up the **RED SPOTS**. (DO NOT TRY TO TURN THIS CONNECTOR).

If the connector is not plugged in, or not correctly plugged in, the display will show CONNECT. If the display still shows the same message when the connector is correctly plugged in, contact your KINETEC distributor as soon as possible. To disconnect, PULL the connector by the milled section.



Starting the unit

Once the display has gone out, press any key to start the KINETEC Maestra Portable.

STOP:

The KINETEC Maestra Portable stops automatically after 2 minutes without being used.

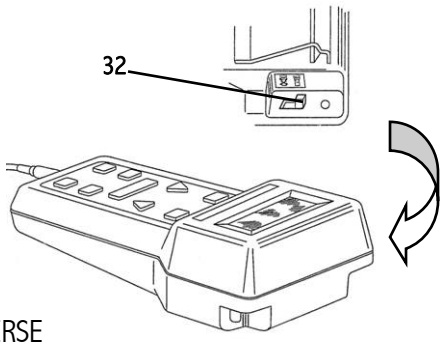
Battery economizing device:

After 2 minutes without the KEYBOARD being used, the display switches off. It can be "activated" by touching any key.

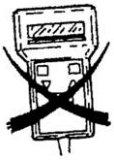
Use of the hand control

Locking the hand control setting

The sliding switch (32) enables or prevents the usage values of the KINETEC Maestra Portable to be modified.



UNLOCKED POSITION
Allows modifications.



LOCKED POSITION
Only the START/STOP/REVERSE
Function usage values may be carried out.

We recommend that you lock the hand control when you give it to the patient.

START/STOP/REVERSE function

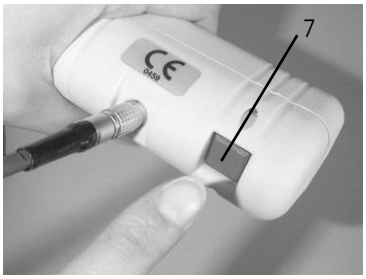
As with all KINETEC systems, KINETEC Maestra Portable is equipped with a START/STOP/REVERSE function.

When the unit is running, the display reads RUN .

START / STOP

Press this key of the hand control. The movement stops.
The display reads STOP .
Press a second time on it.
The movement starts in the opposite direction and the display reads RUN .

This control is repeated with the red button (7) on the motor unit.



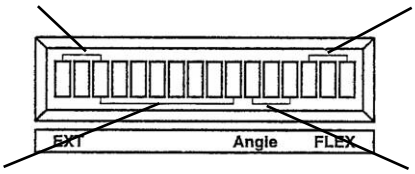
Caution:
For optimum safety, always give the hand control to the patient before starting the system.

Use of the hand control

Display

3 characters show the EXTENSION limit.

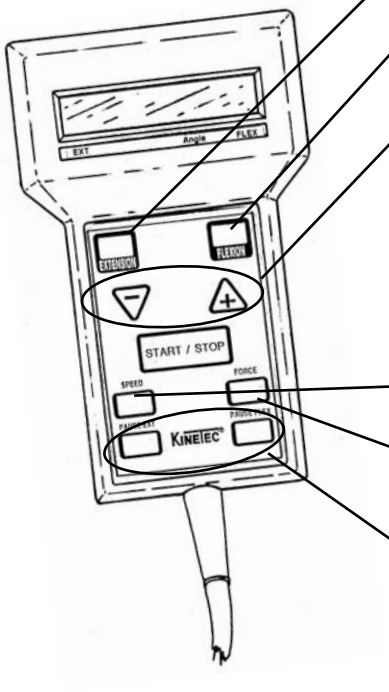
7 characters show messages.
(RUN or STOP or EXT or FLEX or SPEED or FORCE or PAUSE etc).



3 characters show the FLEXION limit.

3 characters show the true angle of the KINETEC Maestra Portable (MP+PIP+DIP).

Key functions



Key for reading or selecting Extension limit — Max.: -15° Extension, Min.: 265° extension

Key for reading or selecting Flexion limit — Max.: 270° Flexion, Min.: -10° Flexion

These keys enable you:
- while selecting, to reduce or increase the operating values,
- while moving [RUN], to exceed the Extension or Flexion limits, it is the BY-PASSING MODE
- at stop, [STOP], to manually move to Extension or Flexion, it is the MANUEL MODE.

To activate the BY-PASSING MODE or MANUAL MODE, press one of two keys for at least 3 seconds. Press the EXTENSION or FLEXION keys to memorize the true angle reached, if necessary.

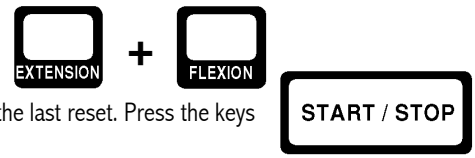
Key for reading or selecting SPEED
Max.: 5=30 seconds, Min.: 1=2 minutes (for a cycle 0° - 270° - 0°).

Key for reading or selecting movement inversion FORCE.
Max.:
Min.:

Key for reading or selecting PAUSE in EXTENSION or FLEXION limit.
Max.: 900 seconds (15min.)
Min.: 0 second

RESET TIME function

Put the switch (32) in the unlocked position.
The splint is at rest [STOP], simultaneously press keys:



This function enables you to read the operating time since the last reset. Press the keys twice to reset the counter.

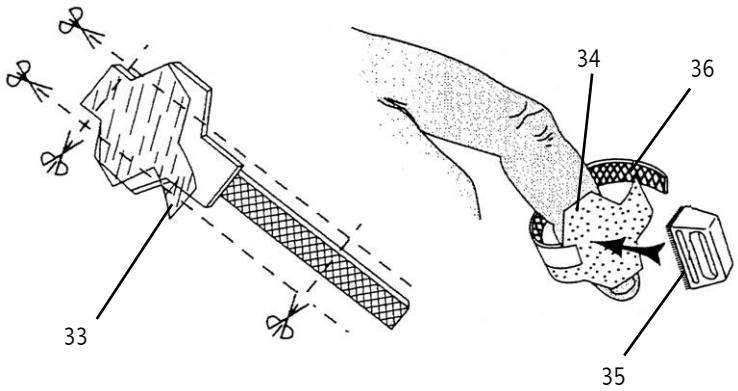
TOTAL TIME function

Put the switch (32) in the unlocked position.
The splint is at rest [STOP], simultaneously press keys.

This function enables you to read the TOTAL operating time.

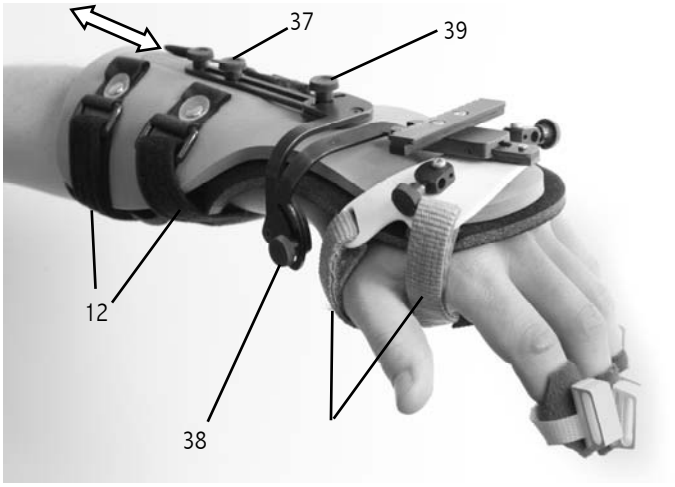
Fitting the finger attachments

- Remove the protective film (33).
- Position the finger attachments (34).
- Cut them out, if required.
- Position the finger slides (35) and, if necessary, pass the Velcro (36) through the slot in slide.



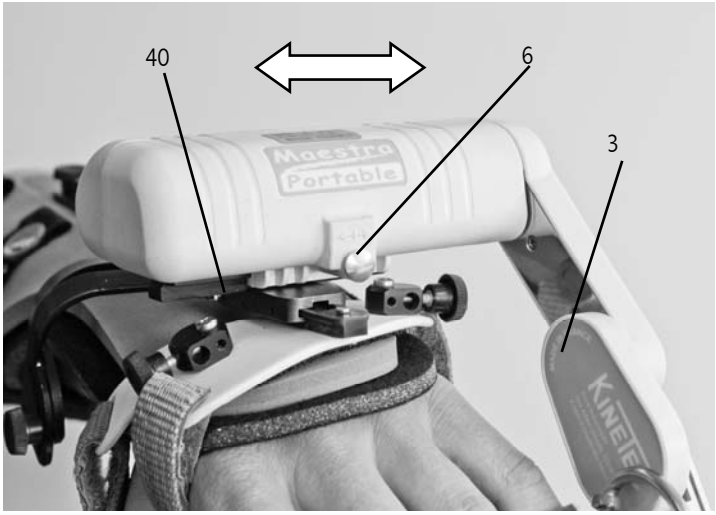
Fitting the splint

- Place the splint on the hand.
- Pull and fold back the straps (11).
- Pull and fold back the straps (12).
- Adjust the position of the splint with the knob (37).
- Adjust the wrist position:
  a - in Flexion/extension:
    - unscrew the knob (38).
    - adjust the position.
    - screw the knob (38).
  b – in Ulnar Deviation:
    - unscrew the knob (39).
    - adjust the position.
    - screw the knob (39).

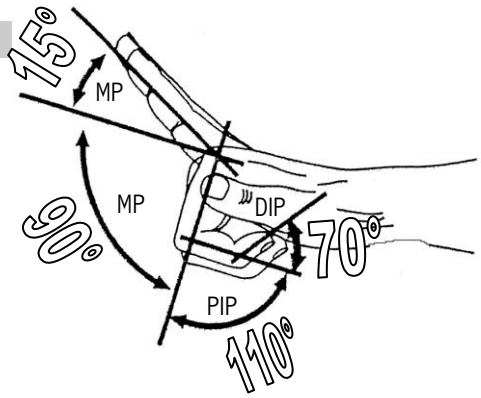


Fitting the motor assembly

- Insert the motor assembly onto the notch bar (40).
- Keep pressing the button (6).
- Slide the unit along to leave a gap of about 1cm (0.4") between the articulating joint (3) and the finger.

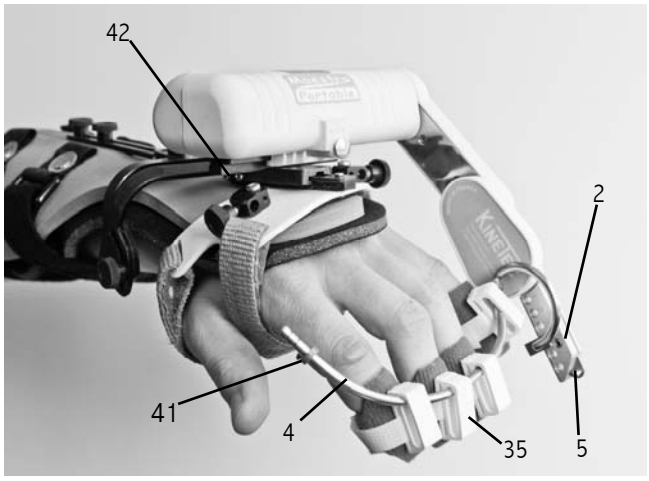


Simultaneous flexion-extension of the three joints: MP, PIP, DIP



The KINETEC Maestra Portable provides a motion from -15° Extension to 270° Flexion.

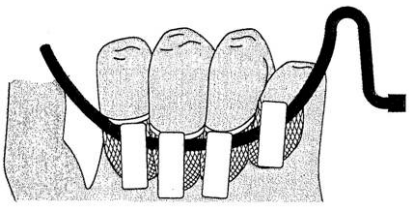
Select the accessories:
For a RIGHT Hand use the Right splint with the GREEN curved bar.
For a LEFT Hand use the Left splint with the RED curved bar.

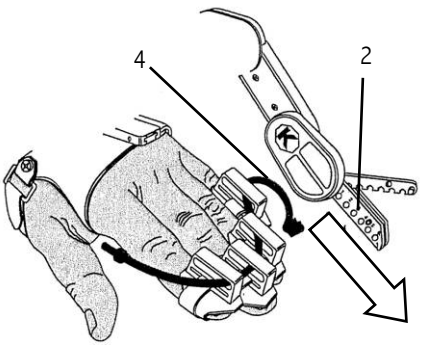


Set up the patient
After fitting the fingers attachments, the splint then the motorization unit (see page 7),
Fitting the curved bar (4), following this process:
- Slip the bar (4) into the finger slides (35).
- Insert the bar into the hole in the drive lever (2), turn down the lock (5).
- Adjust and secure, using the straps (36, see page 7), on the plastic slide.
- If necessary, add the red stop (41).

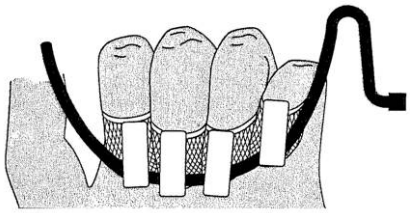
Motion adjustment:
The unit is at the maximum of the R.O.M (270° Flexion)

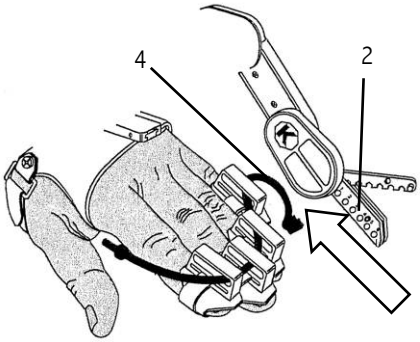
1st Case:
DIP joints are not bent enough, drive-bar is on same level as DIPs.
Put forward the curved bar (4) on the next hole of the drive arm (2).
For a further adjustment, put backward the motor-drive unit, unscrew the 2 screws (42), and adjust the position.
Tighten the screws (42)

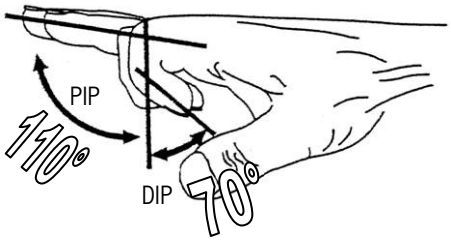




2nd Case:
If the DIP and PIP joints aren't bent enough.
Put forward the curved bar (4) on more hole of the drive arm (2).
For a further adjustment, put forward the motor-drive unit, unscrew the 2 screws (42), and adjust the position.
Tighten the screws (42)

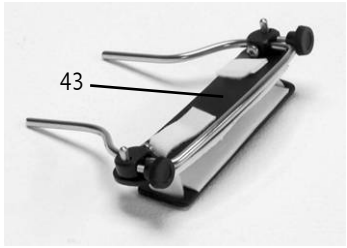




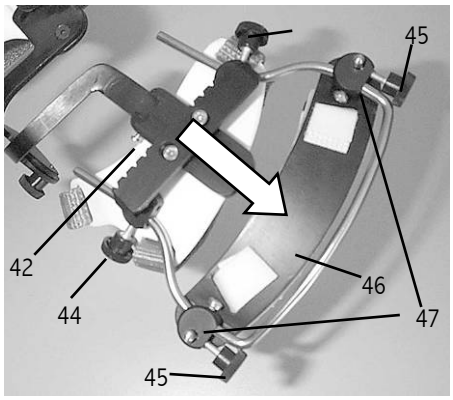


Intrinsic – (PIP, DIP)

The Kinetec Maestra Portable provides a motion from 0° Extension to 180° Flexion.

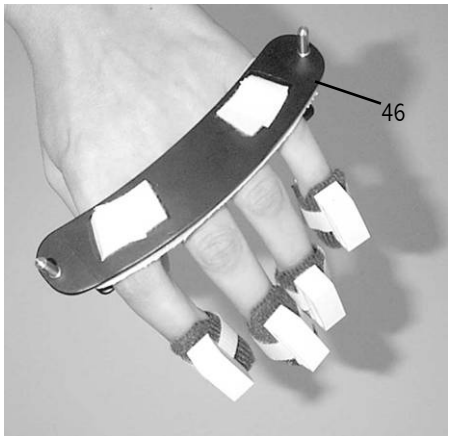


Select the accessories:
For a RIGHT Hand use the Right splint with the GREEN curved bar.
For a LEFT Hand use the Left splint with the RED curved bar.
Use the Intrinsic – accessories (43).

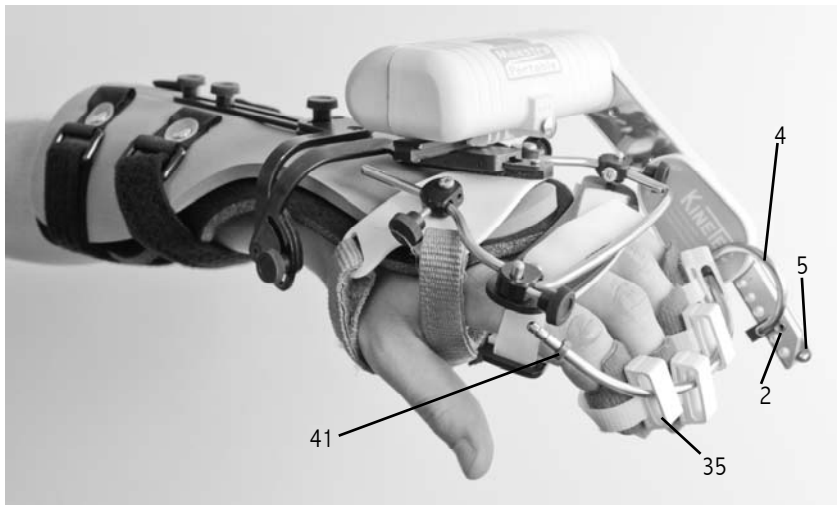


Fitting the accessory:

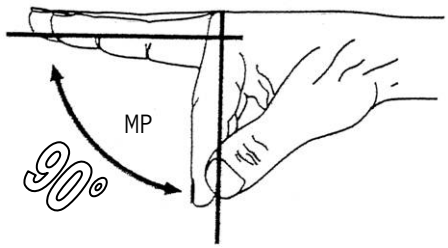
- Attach the accessory using the screws (44) on the hand splint (8).
- Unscrew the screws (45) and put out the plate (46).
- Unscrew the screws (42) and slide the notch bar support following the narrow.
- Tighten the screws (42).



Set up the patient:
- Position the plates (46) on the patient's fingers.
- Fitting the fingers attachments and the splint (see page 7)
- Position the plates (46) on the supports (47).
- Fitting the motor assembly (see page 7).
- Fitting the curved bar (4), following this process:
- Slip the bar (4) into the finger slides (35).
- Insert the bar into the hole in the drive lever (2), turn down the lock.
- Adjust and secure, using the straps (36, see page 7), on the plastic slide.
- If necessary, add the red stop (41).

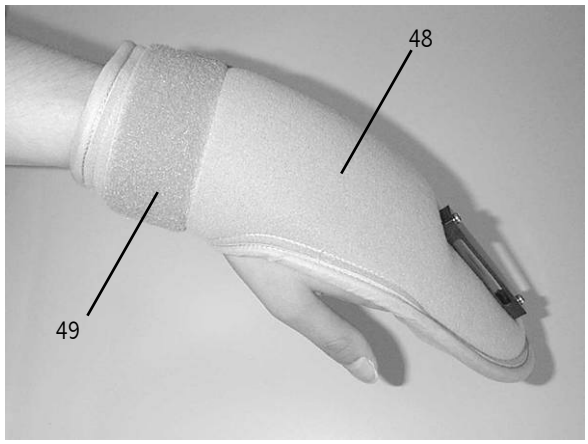


Intrinsic + (MP)



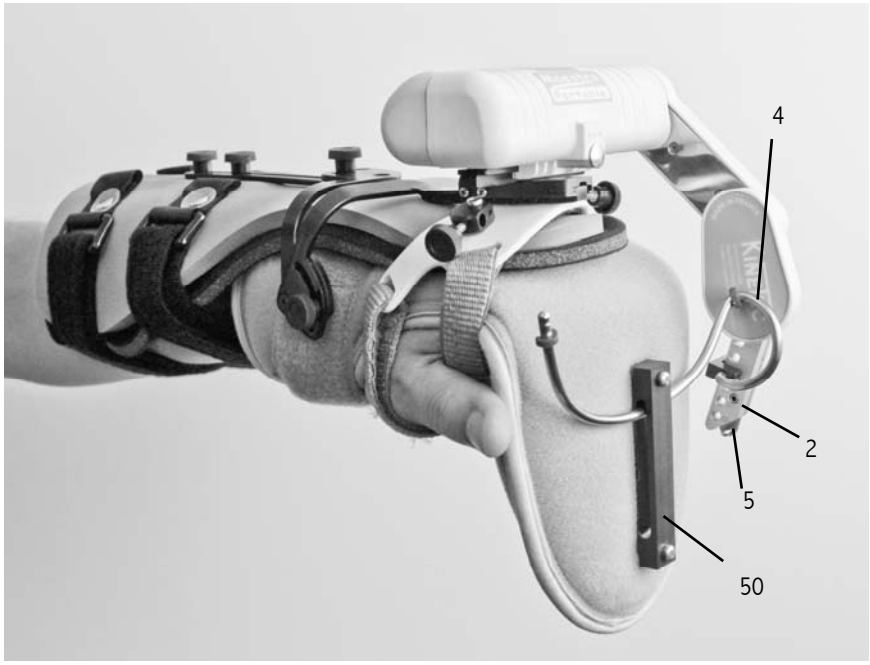
The Kinetec Maestra Portable provides a motion from 0° Extension to 90° Flexion.

Select the accessories:
For a RIGHT Hand use the Right splint with the GREEN curved bar.
For a LEFT Hand use the Left splint with the RED curved bar.
Use the Intrinsic + accessories (48).



Set up the patient:

- Draw on the glove and tighten the strap (49).
- Fitting the splint (see page 7)
- Fitting the motor assembly (see page 7).
- Fitting the curved bar (4), following this process:
- Slip the bar (4) into the slide (50).
- Insert the bar into the hole in the drive lever (2), turn down the lock (5).



Maintenance

The Kinetec Maestra Portable doesn't need maintenance, after 4000 hours of operation, returning the machine to your KINETEC distributor for maintenance is recommended.
In case of electromagnetic interference with other devices move the device.
KINETEC Maestra Portable is in compliance with standards in force (IEC 601.1.2), electromagnetic compatibility standard for medical devices..

Cleaning

Before conducting any cleaning operation, SWITCH the unit OFF, disconnect the power supply and remove the batteries.

Use a DISINFECTANT (PROPANOL/ISOPROPANOL or ALDEHYDE-based solution). Spray the disinfectant on the SURFACES (plastic shells and metal components).

In order to ensure optimal hygiene, you are advised to clean the covers for each new patient. All the softgoods are designed for hazard-free disposal.

Technical specifications

Product:
Weight: 7.7 lbs (3.5 Kg) (without case)
Case dimensions:
12.6 x 16.9 x 5.5 inches
32 x 43 x 14 cm
Angular limits: from -15° extension to 270° flexion (TAM or TPM)
Speed: from 30' to 2' for a cycle of 0°-270°-0°
Patient sizing:
all hand sizes from 7 years to adult.

Electrical:
Power supply: 100-240 V~
Frequency: 50-60 Hz
Power consumption: 1,5 to 7VA
Device of type B class II
IP 20

Environment
- Storage/transport conditions:
Temperature: -40 to 160°F / -40 to 70°C
Relative humidity: up to 90%
- Operating conditions:
Room temperature: 50 to 105°F / 10 to 40°C
Relative humidity: up to 80%

Troubleshooting

A spare parts list and technical catalog are available to you on request from your KINETEC distributor.
If, after starting up the KINETEC Maestra Portable by press any key:

- The display does not indicate any information:
  - Check the good positioning of the batteries or electrical connections.
  - Check that the electrical socket is live using another device.
  - If the display still does not indicate any information, contact your nearest KINETEC technician.
- The display shows CONNECT :
  - Check that the hand control is firmly connected.
  - Make sure that the 2 red points are in a good position.
  - If the display shows again this message, please contact your nearest KINETEC technician.
- Your KINETEC Maestra Portable does not work and the display indicates «50 STOP 25 115», Press START again.
  Your KINETEC Maestra Portable still does not function: Contact your nearest KINETEC technician.
- The display shows: SERVICE D2
  Contact your nearest KINETEC technician.

Symbols used

	TYPE B device (protection against electric shocks)
	Caution (consult the accompanying documents)
	Transformer

Warranty

The KINETEC warranty is strictly limited to the replacement free of charge or repair in the plant of the component or components found to be defective.
KINETEC guarantees its continuous passive motion systems for 1 year against all defects of manufacture from the date of purchase by the consumer.
KINETEC is the only organization able to assess the application of the warranty to its systems.
The warranty will be considered null and void if the device has been used abnormally or under conditions of use other than those indicated in the user's manual.
The warranty will also be considered null and void in the event of deterioration or an accident due to negligence, inappropriate surveillance or inappropriate maintenance, or due to transformation of the equipment or an attempt to repair the equipment.

Maintenance sheet

Serial number: _____

Purchasing date: _____

Date: _____ Operations done: _____

Technician: _____ _____

Running time (see page 18): _____ _____

Exchange parts: _____ _____

_____ _____

Date: _____ Operations done: _____

Technician: _____ _____

Running time (see page 18): _____ _____

Exchange parts: _____ _____

_____ _____

Date: _____ Operations done: _____

Technician: _____ _____

Running time (see page 18): _____ _____

Exchange parts: _____ _____

_____ _____